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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------|
| 09/777,560 | 02/06/2001 | Curtis R. Brandt | 032026-0460 | 8196 |
| 23524 | 7590 | 06/14/2005 | EXAMINER | |
| FOLEY & LARDNER 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497 | | | | CHEN, STACY BROWN |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1648 |

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|----------------------------------|-------------------------|--|
| | 09/777,560 | BRANDT ET AL. | |
| | Examiner Stacy B. Chen | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 September 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) _____ is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some.* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed September 17, 2004 is acknowledged and entered. Claims 1-16 are pending and subject to the following restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I.** Claims 15 and 16, drawn to a method of treating/preventing a viral infection, classified in class 435, subclass 5.

Claims 5-7 and 11-14 link inventions **II-XIII**. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 5-7 and 11-15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. For clarification, claims 5-7 and 11-14 will be examined with the elected Group (II-III). For example, if Applicant elects Group II, claims 1, 2, 9, 10 and linking

claims 5-7 and 11-14 will be examined. If further clarification is required, Applicant is invited to contact the examiner for further explanation.

- II. Claims 1, 2, 9 and 10, drawn to a peptide of SEQ ID NO: 14, classified in class 424, subclass 184.1.
- III. Claim 3, 4 and 9, drawn to a peptide of SEQ ID NO: 15, classified in class 424, subclass 184.1.
- IV. Claim 8, drawn to a peptide of SEQ ID NO: 1 and 2, classified in class 424, subclass 184.1. *Note that SEQ ID NO: 1 and 2 are identical in length and amino acid content. One of SEQ ID NO: 1 and 2 should be deleted since they are identical sequences.*
- V. Claim 8, drawn to a peptide of SEQ ID NO: 3, classified in class 424, subclass 184.1.
- VI. Claim 8, drawn to a peptide of SEQ ID NO: 4, classified in class 424, subclass 184.1.
- VII. Claim 8, drawn to a peptide of SEQ ID NO: 5 and 6, classified in class 424, subclass 184.1. *Note that SEQ ID NO: 5 and 6 are identical in length and amino acid content. One of SEQ ID NO: 5 and 6 should be deleted since they are identical sequences.*
- VIII. Claim 8, drawn to a peptide of SEQ ID NO: 7 and 8, classified in class 424, subclass 184.1.
- IX. Claim 8, drawn to a peptide of SEQ ID NO: 9, classified in class 424, subclass 184.1.

- X. Claim 8, drawn to a peptide of SEQ ID NO: 10, classified in class 424, subclass 184.1.
- XI. Claim 8, drawn to a peptide of SEQ ID NO: 11, classified in class 424, subclass 184.1.
- XII. Claim 8, drawn to a peptide of SEQ ID NO: 12, classified in class 424, subclass 184.1.
- XIII. Claim 8, drawn to a peptide of SEQ ID NO: 13, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and (II-XIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products, peptides, can be used in a materially different method such as in a detection assay for antibodies specific for the various peptides. A detection immunoassay and a method of treating a patient are completely separate methods of use.

Inventions II-XIII are drawn to a peptide of one of SEQ ID NO: 1-15. (Note that SEQ ID NO: 1 and 2 are identical in amino acid content and length, as are SEQ ID NO:5 and 6. SEQ ID NO: 7 and 8 vary in length, but will be examined together if elected). The sequences represented by SEQ ID NO: 1, 3-5, 7 and 9-13 are distinct sequences that vary in amino acid content and length. Each of these sequence encodes a different protein. While the specification discloses that the sequences are related by function (antiviral activity), the actual peptides themselves are

not identical. Therefore, a search for each of SEQ ID NO: 1, 3-5, 7 and 9-13 would require a separate sequence search of patents and non-patent literature, as well as numerous sequence databases. Such a search would be serious burden to the examiner.

Because these inventions are distinct for the reasons given above and the sequence and literature search required for one group is not co-extensive for any other group, and a serious burden to the examiner, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen
June 10, 2005